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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,362	02/16/2000	David Clive Williams	49592 (1878)	6693

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EXAMINER
FORD, JOHN M

ART UNIT	PAPER NUMBER
1624	23

DATE MAILED: 01/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09506362	Applicant(s) D. Williams et al
	Examiner Jim Ford	Group Art Unit 1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 12-31-02 and 1-7-03.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 33--42 and 45--47 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 33--39 and 45--47 is/are allowed.

☒ Claim(s) 40--42 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

Applicants responses of Dec. 31, 2002 and January 7, 2003 are noted.

The claims in the application are claims 33--42 and 45--47.

Claims 33--38 stand allowed.

Claim s 39 and 45--47 are allowed.

Claim 40 is too broadly stated as it reads on all cancer cell lines. In re Hozumi 226 USPQ 353 indicates we cannot allow that breadth.

The Supreme Court declined to expresses a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. V. Manson, (USC 1966) 383 US 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing reasoning the patent system is related to the real World Commerce, rather than the realm of philosophy ibid., 148 USPQ at 696.

The recent utility guidelines set by USPTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is whether the invention has been brought to such perfection as to be capable of practical employment. This language is echoed in Bindra vs. Kelly 206 USPQ 570.

The Patent Office is not precluded from finding an inference of human use and require proof thereof when such use is a medical nature for the treatment of a serious disease, such as cancer. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron, (CCPA 1964) 325 F2d 248, 139 USPQ 516; In re Hartop et al., (CCPA 1962) 311 F2d 135 USPQ 419.

Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven cancer, was held insufficient to establish the utility of claims directed to a method of treating seven cancers. In re Butting, (CCPA 1969) 418 F2d, 163 USPQ 689.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data; the acceptance of the drug employed by the Food and Drug Administration, and by American Medical Association; Ex parte Timmis, (POBA 1959) 123 USPQ 581.

Claims 41 and 42 are rejected, as being dependent on a rejected claim.

To make clearer the lack of enablement for treatment of all cancer, extrinsic evidence is supplied by Draetta (Ann. Reports Med. Chem.), final sentence on page 246 "Although many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely." Since no universal cure for cancer has been developed, it follows that there is no correction between the assays relied upon by applicants and the ability to treat all cancers.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claim 45, does not reasonably provide enablement for claim 40. The specification does not enable one of ordinary skill in the art to use the invention commensurate in scope with claim 40.

The remarkable advances in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the "cancerous cell lines" language means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against all such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

John M. Ford:jmr

January 29, 2003

JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624